

**Notice of Allowability**

Application No.

09/779,957

Examiner

Stuart F. Baum

Applicant(s)

SNELL, KRISTI D.

Art Unit

1638

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to papers filed 1/24/2005.
2. ☒ The allowed claim(s) is/are 1, 6-15, 18, 20-28 (renumber 1-21).
3. ☒ The drawings filed on 12 April 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                              |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>0205</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                                      |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance                                |
|   | 9. <input type="checkbox"/> Other _____  |

Stuart F. Baum

## EXAMINER'S AMENDMENT

### *RCE Acknowledgment*

1. The request filed on 1/24/2005 for a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114, based on parent Application No. 09/779,957 is acceptable and a RCE has been established.

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Brian K. Adams on 2/22/2005.

3. IN THE CLAIMS:

--1. A DNA construct for expression of multiple gene products in a cell comprising:

- (a) a single promoter at the 5' end of the construct [,];
- (b) an intein splicing unit comprising two or more extein sequences encoding ~~one or more~~ separate proteins, and one or more intein sequences fused to the carboxy-terminus encoding portion of each extein sequence, except the last extein sequence to be expressed[,]; and
- (c) a 3' termination sequence comprising a polyadenylation signal following the last extein protein coding sequence[,];

wherein the intein splicing unit is expressed as a precursor protein containing at least one intein flanked by extein encoded proteins; ~~and~~ wherein at least one of the inteins can

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catalyze excision of the exteins; and wherein at least one amino acid residue is substituted in, or added to, the intein splicing unit so that the excised exteins are not ligated by the intein.--

--7. The construct of claim 1 wherein the extein sequences encoding ~~one or more~~ separate proteins are preceded or followed by a sequence encoding a peptide that targets the gene expression product to a particular compartment within the cell in which the construct is expressed.--

--15. A method for expressing multiple genes in cells comprising transforming the cells with a DNA construct comprising:

- (a) a single promoter at the 5' end of the construct[,];
- (b) an intein splicing unit comprising two or more extein sequences encoding ~~one or more~~ separate proteins, and one or more intein sequences fused to the carboxy-terminus encoding portion of each extein sequence, except the last extein sequence to be expressed[,]; and
- (c) a 3' termination sequence comprising a polyadenylation signal following the last extein protein coding sequence;

wherein the intein splicing unit is expressed as a precursor protein containing at least one intein flanked by extein encoded proteins; ~~and~~ wherein at least one of the inteins can catalyze excision of the exteins; and wherein at least one amino acid residue is substituted in, or added to, the intein splicing unit so that the excised exteins are not ligated by the intein.--

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--21. The method of claim 15 wherein the extein sequences encoding ~~one or more~~ separate proteins are preceded or followed by a sequence encoding a peptide that targets the gene expression product to a particular compartment within the cell in which the construct is expressed.--

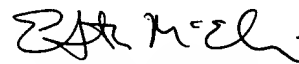
--24. The method of claim 15 wherein the intein splicing unit expression product prevents the ligation reactions normally associated with protein splicing.--

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.  
Patent Examiner  
Art Unit 1638  
February 22, 2005

  
ELIZABETH MCELWAIN  
PRIMARY EXAMINER